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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,157	08/16/2001	Hiroo Imura	299002032411	2951

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EXAMINER

NICHOLS, CHRISTOPHER J.

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,157

Applicant(s)

IMURA ET AL.

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-39 is/are pending in the application.
- 4a) Of the above claim(s) 23-34, 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/121,446.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group VI (claims 35-37) in Paper No. 11 (22 November 2002) drawn to a method of treating a condition characterized by abnormal activity of endothelin receptors in a subject is acknowledged. Claims 23-34 and 38-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11 (22 November 2002).

Status of Application, Amendments, and/or Claims

2. The preliminary amendments of 15 October 2001 (Paper No. 7) and 25 September 2002 (Paper No. 9) have been entered in full. Claims 1-22 are canceled, claims 23-39 have been added, claims 23-34 and 38-39 have been withdrawn from consideration, and claims 35-37 are under examination.

3. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

Information Disclosure Statement

4. The information disclosure statement filed 31 December 2001 (Paper No. 8) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information

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referred to therein has not been considered. Applicant may file replacement copies of the references listed in Paper No. 8 (31 December 2001) with the reply to this office action.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/121446, filed on 14 September 1993.

Specification

6. The Specification is objected to because of the following informalities: handwritten symbols (pp. 6 line 7; pp. 10 lines 29 and 33; pp. 11 line 18; pp. 14 line 30; pp. 16 line 1; pp. 19 lines 1-3). Appropriate correction is required.

Claim Objections

7. Claims 35 and 36 are objected to because of the following informalities: claims 35 and 36 refer to claim 23, a non-elected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 35-37 are directed to a method of treating a condition characterized by abnormal activity of endothelin receptors in a subject comprising the steps of identifying compounds which bind to the endothelin receptor via a cell-based assay and administering the target compound to a subject.
9. The specification teaches that the endothelin receptors have three isoforms: endothelin 1 (ET-1), endothelin 2 (ET-2), and endothelin 3 (ET-3). ET receptors are found in a wide variety of vascular and non-vascular tissues. Hypertension, vasospastic stenocardia, acute myocardial infarction, chronic renal insufficiency, subarachnoid hemorrhage, and hypoxia all show elevated serum levels of endothelin. However, there is no disclosure of a correlation between a specific disease state and endothelin receptor abnormal activity as required by the claims.
10. The art teaches that endothelin is a strong vasoconstrictor. Endothelial, tracheal, kidney, and neuronal tissues all synthesize endothelin. The release of endothelin is stimulated by a variety of chemical and physical stimuli. Numerous compounds can affect endothelin receptors as agonists or antagonists (US 5464853).
11. While the specification supports invention regarding isolation, cloning, expression, and a cell-based assay for the identification of compounds which bind an endothelin receptor no working examples are given re: diseases resulting from abnormal activity of endothelin receptors (SEQ ID NO: 1) or compounds other than endothelin (ET) which bind to SEQ ID NO: 1.

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12. Thus the claimed invention is directed to a method of treating a condition characterized by abnormal activity of endothelin receptors in a subject, which is not supported by the teachings of the prior art. One skilled in this art would be expected to reasonably doubt that the claimed method would work due to the following obstacles: Specific biological actions/activities that the compounds would effect; How does the effect on ET-receptor relate to symptoms of a wide range of disorders; Expectation of ET-receptor to be involved in one or any disorder; The efficacy of any given compound to effect an ET-receptor in sufficient manner to have a therapeutic effect; The evaluation of administering any given compound to a subject. The specification does not provide guidance on how to overcome expected obstacles. The scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure provided by the specification and prior art for the following reasons.

13. Regarding endothelin receptor-related conditions, the art recognizes that altered levels of endothelin are found in ischemic heart disease, advanced atherosclerosis, Buerger's disease, Raynaud's phenomenon, pulmonary hypertension, and patients undergoing surgical procedures such as percutaneous transluminal coronary angioplasty (US 6432994 Col. 4 lines 34-53). However, neither the specification nor the art discloses a correlation between a specific disease and an abnormal activity of the ET receptor, which is what the claims require. Due to the large quantity of experimentation necessary to evaluate all the possible endothelin receptor-related conditions, the lack of direction/guidance presented in the specification which endothelin receptor-related conditions, the absence of working examples directed to endothelin receptor-related conditions, the complex nature of the invention, the unpredictability of the effects of test

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compounds on a endothelin receptor-related condition (US 6432994), and the breadth of the claims which fail to recite limitations for which endothelin receptor-related condition, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

14. Finally, the application must establish a nexus between the compound recited in the claims and the disease state recited in the claims. In this case, the skilled artisan is not guided as to how a compound must affect one or more activates of any ET receptor such that the compound would be determined to be one that alleviates or induces an ET receptor-related condition. It is not clear that any ET binding compound would be involved in a rate-limiting step for any ET related condition such that it could be used to successfully treat an ET receptor-related condition.

Summary

15. Claims 35-37 are hereby rejected.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
January 15th, 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER